REMARKS

Claims 35-38 and 40-60 have been provisionally rejected on the ground of non-statutory obviousness-type double patenting over claims 1-9 and 11-17 of co-pending Application Serial No. 11/430,542. Applicant will file the necessary disclaimer once the claims of Serial No. 11/430,542 are allowed.

Claims 35-38, 40, 42-44, 46, 47, 50-55, 59 and 60 have been rejected under 35 USC 103(a) as "anticipated" by Kawasaki et al. in view of Wagner.

Kawasaki relates to a compressive hemostatic belt designed to press on an insertion wound to stop the bleeding. Accordingly, it is not an ostomy device, as it is not designed to control the passage of liquid and solid waste material through a surgically created opening in the body.

The Examiner's comment with respect to the word "stoma" not being limited to an intestinal opening ignores the fact that the preamble of each of the independent claims states that the function of the ostomy device is to control the passage of liquid and solid waste through the stoma. Further, the body of each of the independent claims requires that the member be adapted to prevent passage of liquid and solid "waste" material through the stoma when pressed against the stoma.

The fact that Kawasaki is a compressive hemostatic belt used to stop bleeding from a catheter insertion wound and is not an "ostomy" device for controlling the passage of liquid and solid waste through the stoma, is itself enough to distinguish over Kawasaki.

Further, even if the wound site is "at least partially covered/surrounded by" adhesive means 14 and 15 of Kawasaki, the Kawasaki belt cannot function as an ostomy

device to control the passage of liquid and solid waste through the stoma. To function properly, the stoma covering means of the claimed ostomy device must completely surround and enclose the stoma such that, when pressed against the stoma, passage of liquid and solid waste through the stoma can be prevented. An adhesive means that only "at least partially" surrounds the stoma would not adequately seal the member to the body, or permit the member to prevent the passage of waste through the stoma, and therefore the ostomy device would not function in an acceptable manner.

Kawasaki discloses adhesive plasters 14 and 15 in the form of strips. It is clear from the Figures 22a and 22b of Kawasaki that plasters 14 and 15 are parallel to and spaced from each other. They do not and cannot completely surround or enclose the wound on all sides.

The Examiner apparently agrees with that as the rejection of the claims under 35 USC 102(b) as anticipated by Kawasaki has been withdrawn and the claims are now rejected under 35 USC 103(a) over Kawasaki in view of Wagner. Wagner, it is stated, teaches providing a seal completely surrounding and enclosing a stoma on all sides and it is now asserted that it would be obvious to one having ordinary skill in the art to modify the seal of Kawasaki as taught by Wagner.

However, that is not the case. Wagner teaches the use of a skin barrier seal which holds the waste collection pouch securely to the body. Wagner notes, at column 2, lines 34-35, that the integrity of the entire appliance is depends on the effectiveness of the skin barrier seal. However, to use such a seal in Kawasaki would destroy the usefulness of the Kawasaki belt because tightly adhering the Kawasaki belt to the skin using the Wagner

skin barrier seal would cause the wound to tear open when the belt is removed, therefore destroying the usefulness of the belt.

It is for that reason that the Kawasaki teaches, at Column 5, starting at line 18, that gauze 10 is placed on the catheter insertion wound after the extraction of the catheter, and then the belt is placed on the gauze such that the pocket fabric 2 of the pocket 3 receiving the balloon 5 is directed to the gauze 10. Thus, the gauze is inserted between the skin and the belt such that the adhesive does not adhere to the skin adjacent the wound or the wound itself. The fabric adhesive plasters 14 and 15 are made as strips and located remotely from each other such that they hold the belt in place. They do not adhere to the wound, or the skin surrounding the wound, so that when the belt is removed the wound is not torn open.

To better highlight this, each of the main claims has been further amended to require that the adhesive means comprise a continuous, uninterrupted adhesive layer situated between and in direct contact with the recess defining means and the skin surrounding the stoma. In Kawasaki, the fabric adhesive plasters are not situated between and in direct contact with the belt and skin.

Accordingly, Kawasaki itself cannot be properly said to anticipate the claims as amended and the combination of Kawasaki and Wagner, if possible, cannot render the claims as amended unpatentable because such a combination would result in a belt which would harm the patient by tearing the insertion wound open as the belt is removed.

Claim 41 is rejected under 35 USC 103(a) as being unpatentable over Kawasaki. Claim 56 is rejected under 35 USC 103(a) as being unpatentable over Kawasaki and

Bergmann. Claim 45 is rejected under 35 USC 103(a) as being unpatentable over Kawasaki.and Bernstein.

However, neither Kawasaki alone, or in combination with any of the secondary references, discloses an ostomy device in accordance with the claims as amended and hence these rejections should be withdrawn for the same reasons as set forth above.

Respectfully submitted,

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